DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0418] 9858 '01 SEP 21 A10:0

Solvay Pharmaceuticals, Inc.; Withdrawal of Approval of Two New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new drug applications (NDAs) held by Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062. In 1997, the agency informed Solvay of its intention to assess the validity of data and information in all of Solvay's pending and approved applications. However, Solvay does not intend to conduct validity assessments of the two NDAs named in this notice because the products are no longer marketed. Solvay has agreed to permit FDA to withdraw approval of the applications, thereby waiving its opportunity for a hearing.

DATES: Effective [insert date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

David Read,

Center for Drug Evaluation and Research (HFD-7),

Food and Drug Administration,

5600 Fishers Lane,

cd0062

NWL1

Rockville, MD 20857,

301-594-2041.

SUPPLEMENTARY INFORMATION: Recently, FDA determined that Solvay submitted untrue statements of material fact in several applications filed with the agency. These findings, along with other information submitted to the agency by Solvay, provided sufficient justification to question the reliability of data in all of Solvay's applications filed with the agency. Solvay was notified in writing of the agency's determinations and its intention to assess the validity of the data and information in all of Solvay's pending and approved applications. The agency offered Solvay the opportunity to permit FDA to withdraw approval, under § 314.150(d) (21 CFR 314.150(d)), of any application not undergoing a validity assessment.

Subsequently, in letters dated February 29, 2000, Solvay requested withdrawal under § 314.150(d) of the following NDAs held by Solvay:

NDA 16-782; Lithonate (lithium carbonate tablets USP) 300 milligrams (mg); and

NDA 16-980; Lithotabs (lithium carbonate tablets USP) 300 mg.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director of the Center for Drug Evaluation and Research

(21 CFR 5.82), approval of the NDA's listed above, and all amendments and supplements thereto, is withdrawn effective [insert date of publication in the FEDERAL REGISTER]. Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action.

Dated: 9/17/01
September 17, 2001.

Janet Woodcock,
Director,
Center for Drug Evaluation and Research.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
Lynette N. Reele

~~J:\PRITZLAF\FRDOCS\LITHOW_D.WPD~~
~~April 10, 2000~~